REMARKS

I. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner stated the following:

> The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
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> The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the... claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed inventions.
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> The instant claims encompass a method that uses "selective immune down regulation" (SIDR). However, the only such reagents/methods for establishing SIDR are those disclosed in the specification, page 17. The claims encompass use of a vast genus of undisclosed agents that could be used to induce selective immune down regulation. Furthermore, even regarding known immunomodulating agents, it is unclear as to what agents could or could not produce selective immune down regulation as per the definition of said term in the specification. The reagent used in the claimed method is defined in terms of a functional activity with no structural information provided. There is no disclosed (or known) correlation between the functional activity and the structure of an agent that can induce "selective immune down regulation". Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. In the instant application, the amino acid itself or isolated peptide is required. See Fiers v. Revel, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Lts., 18 USPQ2d 1016.
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> In view of the aforementioned problems regarding

> description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir.1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, Id. at 1240. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 016 (Fed. Cir.1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: "The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA." See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

Applicants respectfully disagree with the Examiner's assertion that the claims encompass "a vast genus of undisclosed agents". Specifically, Claim 1 states: "A process for producing selective immune down regulation in a subject to an infectious bacterial agent... and comprising a component or components or fragments thereof of

said infectious agent." (emphasis added). Therefore, the agent, as clearly described is an infectious bacterial agent.

In light of this, Applicants believe that the agent is adequately described, and therefore, the claims do comply with the written description requirement. Furthermore, support for use of this infectious bacterial agent is provided in the last two paragraphs of page 32 of the specification.

Claims 1-3 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (WO 96/39176) in view of Katz (US Patent 4,950,469). The Examiner stated the following:

> Chen et al. teach that oral tolerance to autoantigens can be used to treat antibody mediated autoimmune disease wherein the disease involves antibodies which bind the pertinent autoantigen (see claims 1-13, pages 12-14, 40, 41). Oral tolerance is a form of "selective immune down regulation" (see specification, page 17, second paragraph). Chen et al. do not teach that the disease provoking antigen is streptococcus which is involved with the pathogenesis of rheumatic fever. Katz et al. teach that rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues (see column 6, first). Katz teaches that agents which prevent binding of said antibodies could be used to treat rheumatic fever (see column 6, first paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Chen et al. teach that oral tolerance to autoantigens can be used to treat antibody mediated autoimmune disease wherein the disease involves antibodies which bind the pertinent autoantigen whilst Katz teaches that teach that rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues wherein the streptococcal antigens would function as an autoantigen. One of ordinary skill in the art would have been motivated to do the aformentioned because Chen et al. teach use of oral tolerance to prevent antibody responses causing autoimmune diseases and Katz disclose that anti streptococcal antibodies are involved in rheumatic fever and that neutralization of said antibodies could be used to treat said disease.

Regarding applicants comments about what constitutes a proper rejection under 35 USC 103, said comments ignore KSR Int'l Co. v. Teleflex Inc. Regarding applicants comments about Chen et al. and the term autoantigen, Chen et al. state in page 8, lines 18-20 of said page that regarding the term autoantigen that *"The term also includes antigenic substances that induce conditions having the characteristics of an autoimmune disease when administered to mammals."*. Katz et al. teach that rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues. Thus the streptococcal antigen as per disclosed by Katz would constitute an autoantigen as per the definition of said term in Chen et al. In KSR Int'l Co. v. Teleflex Inc., 550 U.S. __, 2007 WL 1237837, at *13 (2007) it was stated that "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill".

Regarding applicants comments, Chen et al. teach that oral tolerance to autoantigens can be used to treat antibody mediated autoimmune disease wherein the disease involves antibodies which bind the pertinent •autoantigen and wherein oral tolerance is a form of "selective immune down regulation" (see specification, page 17, second paragraph). While Chen et al. do not teach that the disease provoking antigen is streptococcus which is involved with the pathogenesis of rheumatic fever, Katz et al. teach that rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues. Chen et al. state in page 8, lines 18-20 of said page that regarding the term autoantigen that *"The term also includes antigenic substances that induce conditions having the characteristics of an autoimmune disease when administered to mammals."*. Regarding applicants comments about "artificial antigens" and animal models, Chen et al. disclose the use of antigens in humans that are associated with human autoimmune diseases (see pages 17-18). Chen et al. teach that oral tolerance to autoantigens can be used to treat antibody mediated autoimmune disease wherein the disease involves antibodies which bind the pertinent autoantigen and wherein oral tolerance is a form of "selective immune down regulation" (see specification, page 17, second paragraph). While Chen et al. do not teach that the disease provoking antigen is streptococcus which is involved with the pathogenesis of rheumatic

fever, Katz et al. teach that rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues. Chen et al. state in page 8, lines 18-20 of said page that regarding the term autoantigen that *"The term also includes antigenic substances that induce conditions having the characteristics of an autoimmune disease when administered to mammals."*.

Katz et al. teach that rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues. Thus the streptococcal antigen as per disclosed by Katz would constitute an autoantigen as per the definition of said term in Chen et al.

Regarding applicants comments, there is currently no limitation in the claims regarding the dosage of antigen that is used in the claimed method. Chen et al. teach that oral tolerance to autoantigens can be used to treat antibody mediated autoimmune disease wherein the disease involves antibodies which bind the pertinent autoantigen and wherein oral tolerance is a form of "selective immune down regulation" (see specification, page 17, second paragraph). Thus, Chen et al. teach a method of "selective immune down regulation". Applicants arguments involve limitations not recited in the claims under consideration. Regarding applicants comments about "high dose feeding", the method of Chen et al. is not limited to a method of "high dose feeding". For example, in claim 1 of Chen et al., the autoantigen is administered at a dosage wherein the autoimmune disease is treated. Thus, the method of Chen et al. does not require "high dose feeding". In fact, Chen et al., page 16, last paragraph teach:

"As will be understood by those skilled in the art, *the dosage will vary with the disease, the antigen administered and may vary with the sex, age, and physical condition of the patient as well as with other concurrent treatments being administered* Consequently, adjustment and refinement on one or both of the dosages used and the administration schedules will be determined based on these factors and especially on the patients response to the treatment. *Such determinations, however, require no more than routine experimentation...*

Furthermore, there is no disclosure in the specification of the instant application that any particular dosage of antigen is required to practice the instant invention in humans. The specification, page

12 states:

"This invention provides a process for producing selective immune down regulation in a subject to an infectious bacterial agent. In this process, a reagent or a combination of reagents capable of producing selective immune down regulation and comprising a component or components or fragments thereof of such infectious agent is introduced to the subject, thereby establishing selective immune down regulation in the subject.".

Thus, the reagent is simply administered at a concentration that results in selective immune down regulation (such as oral tolerance).

Regarding the specification, Example 1, said example is not drawn to the claimed method (it does not use a bacterial antigen) and is therefore irrelevant to the invention under consideration. Said example also refers to a specific dosage range wherein said range is not the dosage encompassed by the term "large amounts of antigen" as per Chen et at. It is also noted that none of the claims under consideration recite the administration of any particular concentration of antigen. Regarding applicants comments about Katz, said reference discloses that rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues (see column 6, first paragraph). Katz then discloses that said disease can be treated using an agent that interferes with said antibodies (see column 6, first paragraph). Thus Katz clearly discloses the role of said antigen in rheumatic fever. In addition, Chen et al. disclose that particular antigens can be identified by screening antigens for binding with antibodies from a patient (see page 18, penultimate paragraph).

Chen et al. teach that oral tolerance to autoantigens can be used to treat antibody mediated autoimmune disease wherein the disease involves antibodies which bind the pertinent autoantigen and wherein oral tolerance is a form of "selective immune down regulation" (see specification, page 17, second paragraph). While Chen et al. do not teach that the disease provoking antigen is streptococcus which is involved with the pathogenesis of rheumatic fever, Katz et al. teach that rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues.

As described in the Office Action, Chen teaches that autoantigens can be used to induce oral tolerance for treatment of disease. As stated in the Office Action, Chen's definition of autoantigens not only includes the antigens that are native to a subject but also "antigenic substances that induce conditions having the characteristics of an autoimmune disease when administered to mammals." It should be noted that since these substances are being "administered", reference is not being made to bacteria that during the course of a natural infection evoke an autoimmune response, but rather to artificial circumstances where a substance is administered to an animal to create an animal model system that mimics an autoimmune disease. (For example collagen for an arthritis model, and myelin basic protein for encephalomyelitis). However, Applicants do not see any reference in either Chen or Katz that describes the isolation of fragments or components of streptococcus (or any other bacterium) and their administration to induce an autoimmune response. Furthermore, Applicants believe that at the present time it is unknown whether antigenic substance derived from streptococcus (i.e. fragments and components) may be administered to a subject or animal model in the absence of an active infection to induce an autoimmune reaction. In the absence of knowledge of this capability, bacterial fragments and components do not fulfill the definition given by Chen for autoantigens. As such, Chen's definition only encompasses endogenous substances that are targets of an autoimmune response and exogenous substances that in themselves are capable of inducing an autoimmune response.

Moreover, Katz only describes a relationship between antigens of Streptococcus and endogenous antigens in a subject which are targets of an autoimmune response. Katz also requires conjugates of antigens with glutamic acid and lysine. There is no indication that in the absence of a modification, such results should be achieved. As such, Applicants believe that neither Chen nor Katz anticipate the present invention.

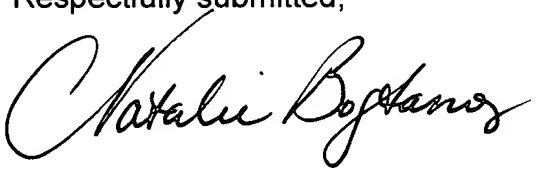
SUMMARY

In view of the foregoing remarks, Applicants respectfully request reconsideration and withdrawal of the rejections of record and further examination of the pending claims. Early and favorable action is respectfully requested.

No other fee or fees are believed due in connection with this paper. In the event that any fee or fees are due, however, the United States Patent and Trademark Office is hereby authorized to charge any such fee or fees to Deposit Account No. 05-1135, or to credit any overpayment thereto.

If a telephone conversation would further the prosecution of the present application, Applicants' undersigned attorney requests that she be contacted at the number provided below.

Respectfully submitted,



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